

EXHIBIT 36

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL) MDL No. 2804
5 PRESCRIPTION OPIATE)
6 LITIGATION) Case No.
7) 1:17-MD-2804
8)
9 THIS DOCUMENT RELATES TO) Hon. Dan A.
10 ALL CASES) Polster
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Tuesday, May 14, 2019

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

Videotaped Deposition of JAMES E.
RAFALSKI, VOLUME 2, held at Weitz &
Luxenburg PC, 3011 West Grand Avenue, Suite
2150, Detroit, Michigan, commencing at
8:25 a.m., on the above date, before
Michael E. Miller, Fellow of the Academy of
Professional Reporters, Registered Diplomate
Reporter, Certified Realtime Reporter and
Notary Public.

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1 understand what this idea of know your
2 customer's customer meant, it couldn't look
3 in the regulations, could it, because it's
4 not there?

5 MR. FULLER: Form.

6 A. I think it's encompassed in the
7 maintenance of effective controls.

8 BY MR. O'CONNOR:

9 Q. But to be clear, the
10 maintenance of effective controls regulation
11 does not mention anything about knowing your
12 customer's customer, does it?

13 A. It doesn't give any specific
14 guidance, but I think what it does is it puts
15 a manufacturer or any registrant on notice
16 that their continued use of a DEA
17 registration requires them to take steps to
18 prevent diversion, and I believe that getting
19 that information is one of those steps.

20 But so just -- just so it --
21 but I guess if your question is does it
22 specifically say that term? It does not.

23 Q. And DEA never issued any
24 guidance to manufacturers informing them of
25 their supposed obligation to monitor -- or to

1 know their customer's customers, correct?

2 MR. FULLER: Form.

3 A. I know I've reviewed where it
4 was presented at some training, but I'm not
5 sure if that was by an industry or a
6 consultant.

7 BY MR. O'CONNOR:

8 Q. DEA --

9 A. So I'll say no.

10 Q. DEA --

11 A. I'm not aware of it. At least
12 I'm not aware they've done it. I'm not
13 saying they have not done it.

14 Q. DEA never published guidance in
15 the Federal Register saying anything about
16 knowing your customer's customer, did it?

17 A. They have not done that.

18 Q. Okay. And they never sent a
19 letter to all manufacturers, for example,
20 saying they were to know their customer's
21 customer, did they?

22 A. I'd like to look at the 2007
23 letter. I think it may say all relevant
24 transaction information, and I would consider
25 that relevant transaction information.

1 Q. But it doesn't say know your
2 customer's customer, does it?

3 A. It does not specifically say
4 that term, no, sir.

5 Q. Okay. In your report, you
6 suggest that: Using relevant data acquired
7 by a manufacturer for compliance purposes is
8 part of maintaining effective controls to
9 prevent diversion. This obligation was
10 acknowledged by Mallinckrodt in its
11 memorandum of agreement Mallinckrodt entered
12 with the United States in 2017.

13 Do you recall that opinion?

14 MR. FULLER: What page are you
15 on, Counsel?

16 MR. O'CONNOR: We're on 146.

17 MR. FULLER: Thank you.

18 A. So your question was -- and I
19 need to read this again, this obligation was
20 acknowledged by Mallinckrodt in the
21 memorandum of agreement Mallinckrodt entered
22 with the United States in 2017?

23 BY MR. O'CONNOR:

24 Q. Correct.

25 A. Yes, I agree with that